

To: Thomas Herrera

From: Craig Caris

Subject: September 18, 2007 Meeting With Ronan Engineering

On behalf of Ronan Engineering, I want to thank you and your staff for the opportunity to discuss the proposed amendment to the RLL-1 Registry. The following items were discussed and clarified during the meeting:

- 1) The amendment for the RLL-1 was to have the current approved leak testing requirements for each configuration of the device moved from page 6 of the Registry to the cover page to avoid confusion. No changes to the device or leak testing requirements is being requested, only a formatting change to the document.
- 2) There are no regulatory requirements mandating leak testing of Generally Licensed devices. Reference 10CFR32.51 (3) (ii) which in summary states that the labeling on each device shall clearly state the requirements for, or lack of requirement, for leak testing, or for testing of the on/off mechanism. This ties back to 10CFR 31.5(c)(2) which in summary states that leak testing shall be conducted ever 6 months or as specified on the label.
- 3) Special form sources are tested and approved for use under certain environmental conditions and if these environmental conditions are not exceeded the capsule integrity should be maintained throughout its useful life.

Cc:

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